

National Cancer Institute
Institutional Review Board

AGENDA
AUGUST 19, 2013
1:00 – 5:30 pm
CRC/3-1608

- 1. Review of Draft Minutes, August 5, 2013**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Unanticipated Problems/Protocol Deviations**
- 6. Other Expedited Actions**
- 7. Continuing Reviews/Terminations**
- 8. Response to Stips** 10C0174-H, "Related and Unrelated Donor Hematopoietic Stem Cell Transplant for DOCK8 Deficiency" - Dennis Hickstein, PI
- 9. Amendment** 13C0132-C, "Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC syndrome" - Dennis Hickstein, PI
- 10. Amendment** 13C0063-A, "A Phase I, Open-label, Multiple-Ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C, a Monoclonal anti-PD-L1 antibody, in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications" - James Gulley, PI
- 11. Amendment** 12C0004-E, "A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma" - Teri Nguyen Kreisl, PI
- 12. Amendment** 11C0162-F, "A Multicenter, Open-label, Phase 2, Safety and Efficacy Study of the Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Subjects with Relapsed or Refractory de novo Diffuse Large B-cell Lymphoma" - Wyndham Wilson, PI
- 13. Amendment** 08C0123-L "A Phase 1, Multicenter, Dose Escalation Study of CAT-8015 in Children, Adolescents and Young Adults with Refractory CD22+ Acute Lymphoblastic Leukemia (ALL) or Non-Hodgkin's Lymphoma (NHL)" - Nirali Shah, PI

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- 14. Amendment** 13C0064-A, "An Open-Label, Multicenter, Single-Arm, Phase I Dose-Escalation with Efficacy Tail Extension Study of RO5185426 in Pediatric Patients with Surgically Incurable and Unresectable Stage IIIC or Stage IV Melanoma Harboring BRAFV600 Mutations" - Melinda Merchant, PI

- 15. Amendment** 02C0212-P, "Clinical, Genetic, Behavioral, Laboratory and Epidemiologic Characterization of Individuals and Families at High Risk of Breast/Ovarian Cancer" - Mark Greene, PI

- 16. Amendment** 04C0055-BB, "Allogeneic HSCT Without Preparative Chemotherapy or With Low-Intensity Preparative Chemotherapy Using Sirolimus and Sirolimus Generated Donor Th2 Cells for Therapy of Refractory Leukemia, Lymphoma, Myeloma, or Myelodysplastic Syndrome"—Daniel Fowler, PI

- 17. Initial Review** P131385, "A Phase II Study of Cell Transfer Therapy for Metastatic Melanoma Using 41BB Selected Tumor Infiltrating Lymphocytes Plus IL-2 Following a Non-Myeloablative Lymphocyte Depleting Chemotherapy Regimen" - Steve Rosenberg, PI

- 18. Initial Review** P131353, "A Phase 2, Randomized, Double-blind Study Comparing Tremelimumab to Placebo in Second- or Third-line Treatment of Subjects with Unresectable Pleural or Peritoneal Malignant Mesothelioma " - Raffit Hassan, PI

- 19. Initial Review** P121103, "A Pilot Study of Metformin in Patients with a Diagnosis of Li-Fraumeni Syndrome " - Tito Fojo, PI